and

[(d) the following sequence of ORF-2:

Met-Glu-Pro-Val-Asp-Pro-Arg-Leu-Glu-Pro-Trp-Lys-His-Pro-Gly-Ser-Gln-Pro-Lys-Thr-Ala-Cys-Thr-Thr-Cys-Tyr-Cys-Lys-Lys-Cys-Cys-Phe-His-Cys-Gln-Val-Cys-Phe-Thr-Thr-Lys-Ala-Leu-Gly-Ile-Ser-Tyr-Gly-Arg-Lys-Lys-Arg-Arg-Gln-Arg-Arg-Arg-Pro-Pro-Gln-Gly-Ser-Gln-Thr-His-Gln-Val-Ser-Leu-Ser-Lys-Gln; and]

[(e)] (d) the peptide having the following sequence of ORF-4:

Met-Gln-Pro-Ile-Gln-Ile-Ala-Ile-Ala-Ala-Leu-Val-Val-Ala-Ile-Ile-Ile-Ala-Ile-Val-Val-Trp-Ser-Ile-Val-Ile-Ile-Glu-Tyr-Arg-Lys-Ile-Leu-Arg-Gln-Arg-Lys-Ile-Asp-Arg-Leu-Ile-Asp-Arg-Leu-Ile-Glu-Arg-Ala-Glu-Asp-Ser-Gly-Asn-Glu-Ser-Glu-Gly-Glu-Ile-Ser-Ala-Leu-Val-Glu-Met-Gly-Val-Glu-Met-Gly-His-His-Ala-Pro-Trp-Asp-Ile-Asp-Asp-Leu.

REMARKS

Applicants respectfully request reconsideration and reexamination of this application.

Claims 11, 13, and 15 have been amended to recite "a peptide" rather than "an amino acid sequence," and to delete the recitation of a peptide having the sequence of ORF-2. Applicants have deleted the recitation of "ORF-2", or "*tat* protein" for the sole purpose of advancing the prosecution of this case. Applicants reserve the right to prosecute this

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subject matter in another application. Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

This application is directed to antibodies which bind with a peptide of HIV-1 corresponding to ORF-Q, ORF-R, ORF-1, and ORF-4; antibodies that bind with immune complexes comprising peptides of HIV-1 corresponding to ORF-Q, ORF-R, ORF-1, and ORF-4; and immunological complexes comprising a peptide of HIV-1 corresponding to ORF-Q, ORF-R, ORF-1, or ORF-4. The antibodies of the invention are useful, for example, for screening compositions for synthetic or natural peptides encoded by ORF-Q, ORF-R, ORF-1, and ORF-4 of HIV-1. Synthetic production of these peptides is described at, for example, page 15, lines 18-24 of the specification. In addition, the antibodies can be used for screening biological samples for the presence of ORF-Q, ORF-R, ORF-1, and ORF-4 of HIV-1. The immune complexes are useful to obtain the component antibody or antigen.

Claims 11, 13, and 15 were rejected under 35 U.S.C. § 101 as the claimed invention allegedly lacks diagnostic utility. Paper No. 12 at 2. Applicants respectfully traverse this ground for rejection.

The Examiner stated that the rejection of claims 11, 13, and 15 under § 101 as lacking diagnostic utility "is maintained for reasons previously set forth." Paper No. 12 at 2. In particular, the Examiner stated that

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> [t]he rejection is mainly applicable for the portion of the claim relating to the use of the antibodies to the *tat* protein. *tat* is the product of a spliced gene. . . . There is no convincing evidence that the product of the sequence in the claims would yield a *tat* product which can elicit antibodies that are of diagnostic value, for reasons adequately discussed in paper #10.

Paper No. 12 at 2. Applicants courteously disagree.

In Paper No. 10, the Examiner argued that applicants' claimed antibodies and immune complexes lack utility because the peptides recited in the claims "have not been shown to be expressed in biological samples, and there is no practical utility associated with screening for peptides which do not occur in nature, especially with respect to HIV related peptides." Paper No. 10 at 2.

In response, applicants argued that because the ORF regions recited in the claims encode proteins of HIV-1, the claimed invention has utility. Specifically, ORF-Q corresponds to *vif* protein, ORF-R corresponds to *nef* protein, ORF-1 corresponds to *vpr* protein, and ORF-4 corresponds to *vpu* protein of HIV-1. Amendment filed August 4, 1994 at pages 2-5.

The Examiner's response only addresses the reactivity of the *tat* peptide recited in the claims. Claims 11, 13, and 15 have been amended to delete the recitation of a peptide corresponding to the *tat* region of HIV-1 for the sole purpose of advancing the prosecution of this case. In view of the foregoing amendments and remarks, withdrawal of this ground for rejection is respectfully requested.

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The specification was objected to and claims 11, 13, and 15 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an enabling disclosure. Paper No. 12 at 3. Applicants respectfully traverse this ground for rejection.

The Examiner first stated that

> [t]he specification . . . does not discuss the possibility of split ORFs in producing a particular gene product. It is now known that *tat* is a product of two different ORFs, however, this was not known at the time the invention was made.

Paper No. 12 at 3.

While applicants respectfully disagree with the Examiner's argument, claims 11, 13, and 15 have been amended to delete the recitation of ORF-2, which corresponds to the *tat* gene encoded by a split gene.

Continuing, the Examiner stated that

> it was not clear what form of expression or the expression system would have been capable of appropriately expressing the various gene products. The specification fails to provide enablement in the form of guidance in determining how to effectively make the claimed antibodies, through appropriate analysis and expression of the gene products. One of ordinary skill in the art would have been forced into undue experimentation to make the claimed invention as the specification was not enabling at the time the invention was made.

Paper No. 12 at 3 and 4. Applicants respectfully disagree.

The specification need not include that which is already known by and available to the public. Paperless Accounting,

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Inc. v. Bay Area Rapid Transit System, 804 F.2d 659, 664, 231 U.S.P.Q. 649 (Fed. Cir. 1986). In fact, techniques that were old and well-known when the application was filed need not be included in the specification, and are preferably omitted. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534, 3 U.S.P.Q.2d 1737 (Fed. Cir. 1987).

An Examiner may properly lodge a rejection of claims as based on a specification that is not in compliance with § 112, first paragraph, if it appears reasonable to conclude that one skilled in the art would have been unable to make or use the invention at the time the application was filed. When that conclusion is reasonable, the burden is on the applicant to rebut it, if he can, such as by offering evidence. In re Eynde, 178 U.S.P.Q. 470, 474 (C.C.P.A. 1975).

The patent applicant can carry this burden by showing that a person of ordinary skill in the art possessed of the knowledge available at the time of filing could practice the invention without undue experimentation. Id. "A patent applicant may offer evidence, such as patents and publications, to show the knowledge possessed by those skilled in the art and thereby establish that a given specification disclosure is enabling." Id.; emphasis added.

Conversely, if the information required to practice the invention is not well-known in the art, the application itself must contain the information. In re Buchner, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991). Thus, if applicants had to rely on

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unknown or unconventional techniques for carrying out their invention, their patent application would have to describe these techniques. This is not such a case.

Exemplary expression techniques are described by Maniatis et al., "Synthesis and Cloning of cDNA," Molecular Cloning: A Laboratory Manual, pages 211-246 (Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, 1982) (Exhibit 1); and Gray et al., "Open Reading Frame Cloning: Identification, Cloning, and Expression of Open Reading Frame DNA," Proc. Natl. Acad. Sci. USA, 79, 6598-6602 (1982) (Exhibit 2). Both of these references were published before applicants' earliest claimed priority date.

Because expression and cloning techniques for open reading frame DNA were known in the art at the time the application was filed, such techniques need not be described in the application to satisfy § 112, first paragraph. As stated by the court in In re Bosy, 149 U.S.P.Q. 789, 792 (C.C.P.A. 1966): "That which is common and well known is as if it were written out in the patent." Withdrawal of this ground for objection to the specification and rejection of the claims is respectfully requested.

Reconsideration and reexamination of this application, and allowance of the pending claims at the Examiner's convenience, are courteously requested.

If there are any fees due in connection with the filing of this Response, please charge such fees to our Deposit Account

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No. 06-0916. If a fee is required for an Extension of Time under 37 C.F.R. § 1.136 not accounted for above, such an Extension is requested and fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: December 20, 1994

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